DEC 1 9 2003

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is ~~Not Assigned~~ K031260

1. Device Name

Classification Name:	Glucose Test System (§ 862.1345)
Common/Usual Name:	Blood Glucose Meter and Reagent Test Strips
Proprietary Names:	Freestyle™Blood Glucose Monitoring System And FreeStyle Tracker Diabetes Management System

2. Legally Marketed Devices to which Substantial equivalence is Claimed:

Predicate Device	510(k) Number
Freestyle™Blood Glucose Monitoring System	K992684 K000582 K012014
FreeStyle Tracker Diabetes Management System	K020866

3. Device Description

The FreeStyle Blood Glucose Monitoring System comprises an electrochemical biosensor glucose reagent test strip, a handheld meter, a quality control solution, a complete Owner's Booklet and Quick Reference Guide. A lancing device, lancets and a logbook for recording test results are also included with the system.

When the user inserts a test strip, the meter turns on. The user acquires a blood sample (with the test strip in the meter) by picking up the meter and touching the edge of the test strip at the blood target area, filling the chamber on the strip by capillary action. The meter sounds a tone (bee) to let the user know that the sample chamber is full and the reaction has begun. When the test is complete, the meter displays the glucose reading on its liquid crystal display (LCD).

4. Intended Use of the Device

FreeStyle Blood Glucose Monitoring System

The TheraSense, Inc., FreeStyle Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

FreeStyle Tracker Diabetes Management System

The TheraSense, Inc., FreeStyle Tracker Diabetes Management System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Additionally, the TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in home and clinical setting to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program.

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

5. Principle of Operation

The user obtains a blood sample using a conventional lancing technique on the finger or arm. The user inserts a test strip into the meter, which turns the meter on. When the strip is touched to the blood drop, the sample chamber on the strip fills by capillary action in approximately 2 seconds. The blood sample volume required is approximately 0.3 microliters (300 nanoliters), which can be obtained from the finger or other areas of the body such as the arm. Test results are displayed in about 15 seconds. The time required to

display test results varies depending on the blood glucose concentration (approximately 15 to 45 seconds).

The glucose in the blood sample reacts with the glucose Dehydrogenase enzyme to yield gluconolactone, and produces a small electrical current. This current is measured by the FreeStyle meter and displayed as a glucose level.

6. Conclusion Drawn from Clinical Test Demonstrating Substantial Equivalence

The clinical study data demonstrate that during times of rapid glucose change, palm and fingertip glucose values are the same. This study confirms results in several published reports which show the equivalence of fingertip and palm glucose test results under conditions of rapid glucose change. The combination of TheraSense's confirmatory study and published support TheraSense's proposed labeling change to recommend the palm of the hand as an alternative test site even under conditions of rapidly changing blood glucose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 9 2003

Ms. Donna K. Templeman
Director, Regulatory Affairs
TheraSense, Inc.
1360 South Loop Road
Alameda, CA 94502

Re: k031260
Trade/Device Name: FreeStyle Blood Glucose Monitoring System and Tracker Diabetes Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; LFR; JJX
Dated: September 16, 2003
Received: September 22, 2003

Dear Ms. Templeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K031260

Device Name: **FreeStyle Blood Glucose Monitoring System and Tracker Diabetes Management System**

Indication for Use:

FreeStyle Blood Glucose Monitoring System

The TheraSense, Inc., FreeStyle Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

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The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf and hand.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-The-Counter Use** X

(Per 21 CFR 801.109)

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

(Optional Format 1-2-96)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031260